

and manner specified by HHS, evidence that its risk adjustment entity meets these standards.

(e) *Timeframes.* A State, or HHS on behalf of the State, must implement risk adjustment for the 2014 benefit year and every benefit year thereafter. For each benefit year, a State, or HHS on behalf of the State, must notify issuers of risk adjustment payments due or charges owed annually by June 30 of the year following the benefit year.

(f) *State summary reports.* Each State operating a risk adjustment program must submit to HHS an annual summary of risk adjustment program operations in the manner and timeframe specified by HHS.

[77 FR 17247, Mar. 23, 2012, as amended at 78 FR 15527, Mar. 11, 2013]

§ 153.320 Federally certified risk adjustment methodology.

(a) *General requirement.* Any risk adjustment methodology used by a State, or HHS on behalf of the State, must be a Federally certified risk adjustment methodology. A risk adjustment methodology may become Federally certified by one of the following processes:

(1) The risk adjustment methodology is developed by HHS and published in the applicable annual HHS notice of benefit and payment parameters; or

(2) An alternate risk adjustment methodology is submitted by a State in accordance with § 153.330, reviewed and certified by HHS, and published in the applicable annual HHS notice of benefit and payment parameters.

(b) *Publication of methodology in notices.* The publication of a risk adjustment methodology by HHS in an annual HHS notice of benefit and payment parameters or by a State in an annual State notice of benefit and payment parameters described in subpart B of this part must include:

(1) A complete description of the risk adjustment model, including—

(i) Factors to be employed in the model, including but not limited to demographic factors, diagnostic factors, and utilization factors, if any;

(ii) The qualifying criteria for establishing that an individual is eligible for a specific factor;

(iii) Weights assigned to each factor; and

(iv) The schedule for the calculation of individual risk scores.

(2) A complete description of the calculation of plan average actuarial risk.

(3) A complete description of the calculation of payments and charges.

(4) A complete description of the risk adjustment data collection approach.

(5) The schedule for the risk adjustment program.

(c) *Use of methodology for States that do not operate a risk adjustment program.* HHS will specify in the annual HHS notice of benefit and payment parameters for the applicable year the Federally certified risk adjustment methodology that will apply in States that do not operate a risk adjustment program.

[77 FR 17247, Mar. 23, 2012, as amended at 78 FR 15528, Mar. 11, 2013]

§ 153.330 State alternate risk adjustment methodology.

(a) *State request for alternate methodology certification.* (1) A State request to HHS for the certification of an alternate risk adjustment methodology must include:

(i) The elements specified in § 153.320(b);

(ii) The calibration methodology and frequency of calibration; and

(iii) The statistical performance metrics specified by HHS.

(2) The request must include the extent to which the methodology:

(i) Accurately explains the variation in health care costs of a given population;

(ii) Links risk factors to daily clinical practice and is clinically meaningful to providers;

(iii) Encourages favorable behavior among providers and health plans and discourages unfavorable behavior;

(iv) Uses data that is complete, high in quality, and available in a timely fashion;

(v) Is easy for stakeholders to understand and implement;

(vi) Provides stable risk scores over time and across plans; and

(vii) Minimizes administrative costs.

(b) *Evaluation criteria for alternate risk adjustment methodology.* An alternate risk adjustment methodology will be

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certified by HHS as a Federally certified risk adjustment methodology based on the following criteria:

(1) The criteria listed in paragraph (a)(2) of this section;

(2) Whether the methodology complies with the requirements of this subpart D;

(3) Whether the methodology accounts for risk selection across metal levels; and

(4) Whether each of the elements of the methodology are aligned.

(c) *State renewal of alternate methodology.* If a State is operating a risk adjustment program, the State may not implement a recalibrated risk adjustment model or otherwise alter its risk adjustment methodology without first obtaining HHS certification.

(1) Recalibration of the risk adjustment model must be performed at least as frequently as described in paragraph (a)(1)(ii) of this section;

(2) A State request to implement a recalibrated risk adjustment model or otherwise alter its risk adjustment methodology must include any changes to the parameters described in paragraph (a)(1) of this section.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15528, Mar. 11, 2013]

§ 153.340 Data collection under risk adjustment.

(a) *Data collection requirements.* If a State is operating a risk adjustment program, the State must collect risk adjustment data.

(b) *Minimum standards.* (1) If a State is operating a risk adjustment program, the State may vary the amount and type of data collected, but the State must collect or calculate individual risk scores generated by the risk adjustment model in the applicable Federally certified risk adjustment methodology;

(2) If a State is operating a risk adjustment program, the State must require that issuers offering risk adjustment covered plans in the State comply with data privacy and security standards set forth in the applicable risk adjustment data collection approach; and

(3) If a State is operating a risk adjustment program, the State must ensure that any collection of personally

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identifiable information is limited to information reasonably necessary for use in the applicable risk adjustment model, calculation of plan average actuarial risk, or calculation of payments and charges. Except for purposes of data validation, the State may not collect or store any personally identifiable information for use as a unique identifier for an enrollee's data, unless such information is masked or encrypted by the issuer, with the key to that masking or encryption withheld from the State. Use and disclosure of personally identifiable information is limited to those purposes for which the personally identifiable information was collected (including for purposes of data validation).

(4) If a State is operating a risk adjustment program, the State must implement security standards that provide administrative, physical, and technical safeguards for the individually identifiable information consistent with the security standards described at 45 CFR 164.308, 164.310, and 164.312.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15528, Mar. 11, 2013]

§ 153.350 Risk adjustment data validation standards.

(a) *General requirement.* The State, or HHS on behalf of the State, must ensure proper implementation of any risk adjustment software and ensure proper validation of a statistically valid sample of risk adjustment data from each issuer that offers at least one risk adjustment covered plan in that State.

(b) *Adjustment to plan average actuarial risk.* The State, or HHS on behalf of the State, may adjust the plan average actuarial risk for a risk adjustment covered plan based on errors discovered with respect to implementation of risk adjustment software or as a result of data validation conducted pursuant to paragraph (a) of this section.

(c) *Adjustment to charges and payments.* The State, or HHS on behalf of the State, may adjust charges and payments to all risk adjustment covered plan issuers based on the adjustments calculated in paragraph (b) of this section.